

REMARKS

The Official Action dated June 2, 2008 has been carefully considered. Accordingly, the present Amendment is believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present amendment, claim 1 is amended to positively recite the chain-lengthening reaction product is a chain-lengthened ring-opening polymer in which the oxazoline compound is bonded as a chain-lengthening agent, as set forth throughout the present specification, for example at page 14, line 23-page 15, line 15. Claims 1 and 11 have also been amended to recite that the ratio (Mw_2/Mw_1) is 1.65 to 10.00, as disclosed in the present specification at page 17, line 7. Since these changes are believed to avoid any introduction of new matter, entry of the amendments is in order and is respectfully requested.

Claim 1 was objected to for the recitation that the molecular weight before chain-lengthening is at least 30,000, the Examiner noting that the highest ratio of Mw_2/Mw_1 is 5.00 and the lowest Mw_2 after chain lengthening is 181,000. With the lowest Mw_2/Mw_1 being 5.00 and the lowest Mw_2 being 181,000, the lowest Mw_1 could only be 36,200. As noted above, claims 1 and 11 have been amended to recite that the ratio (Mw_2/Mw_1) is 1.65 to 10.00, as disclosed in the present specification at page 17, line 7. Accordingly, the objection to claim 1 has been overcome. Reconsideration is respectfully requested.

Claims 1, 5, 7, 10, 11, 18, 23, 24, 26 and 28-31 are presently pending. As defined by claim 1, the present invention relates to a high-molecular weight aliphatic polyester, whose molecular weight has been highly increased. The high-molecular weight polyester comprises a

chain-lengthening reaction product of (a) a ring-opening (co)polymer of glycolide or a mixture containing at least 70% by weight of glycolide and at most 30% by weight of another cyclic monomer, and (b) an oxazoline compound having at least two oxazoline ring structures in its molecule. The chain-lengthening reaction product is a chain-lengthened ring-opening polymer in which the oxazoline compound is bonded as a chain-lengthening agent to the extent that a ratio (Mw_2/Mw_1) of a weight average molecular weight (Mw_2) of the ring-opening (co)polymer after the chain lengthening to a weight average molecular weight (Mw_1) of the ring-opening (co)polymer before the chain lengthening is 1.65 to 10.00.

The ring-opening (co)polymer has a weight average molecular weight of at least 30,000 before the chain lengthening and is subjected to the chain-lengthening reaction to produce the high-molecular weight ring-opening (co)polymer. The weight average molecular weight (Mw) of the ring-opening (co)polymer after the chain lengthening, whose molecular weight has been increased by the chain-lengthening reaction, is 181,000 to 500,000. A molecular weight distribution (Mw/Mn) represented by a ratio of a weight average molecular weight (Mw) of the ring-opening (co)polymer, whose molecular weight has been highly increased by the chain-lengthening reaction, to a number average molecular weight (Mn) thereof is 2.30 to 4.50. A difference ($T_2 - T_1$) between a 1%-weight loss-starting temperature T_2 on heating of the ring-opening (co)polymer after the chain lengthening and a 1%-weight loss-starting temperature T_1 on heating of the ring-opening (co)polymer before the chain lengthening is 15°C to 30°C.

According to the present invention, high-molecular weight polyglycolic acid (polyglycolide) can be obtained by the chain-lengthening reaction using the oxazoline

compound. Generally, it is difficult to obtain a high-molecular weight polyglycolide using ring-opening polymerization of glycolide. However, according to the present invention, the high molecular weight product is obtained as a comprising a chain-lengthened ring-opening polymer in which the oxazoline compound is bonded as a chain-lengthening agent. The thus defined high-molecular weight aliphatic polyester is excellent in mechanical strength and exhibits markedly improved heat resistance, as demonstrated by $T_2 - T_1$ of 15°C to 30°C. Accordingly, the polyester may be used in a wide variety of fields as extruded products, compression-molded products, injection-molded products, blow-molded products and composite materials (see, for example, the present specification at page 25, lines 5-13).

As defined by claim 11, in the process for producing a high-molecular weight aliphatic polyester according to the present invention, the ring-opening (co)polymer and 1 to 10 parts by weight of the oxazoline compound per 100 parts by weight of the ring-opening (co)polymer are subjected to the chain-lengthening reaction under conditions wherein the reaction temperature is not lower than the melting temperature of the ring-opening (co)polymer, but not higher than 300°C, and the reaction time is 10 to 30 minutes. By this process, a high-molecular weight ring-opening (co)polymer having the above properties is obtained. A comparison of Examples 1 and 2 with Example 3 at pages 22-24 shows that the claimed properties are not inherent in all reaction products of a ring-opening (co)polymer of glycolide and an oxazoline compound, but are provided by the production process of claim 11.

Claims 1, 5, 7, 10 and 29-31 were rejected under 35 U.S.C. §102(b) as being anticipated by the Matsumoto et al Japanese Reference No. JP 2001/323056. Claims 11, 18, 23, 24, 26 and

28 were rejected 35 U.S.C. §103(a) as being unpatentable over Matsumoto et al. The Examiner asserted that 2 wt % oxazoline is disclosed in Example 6 of Matsumoto et al and that the end product requirements of MW of 100,000 to 300,000 are disclosed in paragraph [0010], and concluded the property requirements are inherent.

These rejections are traversed and reconsideration is respectfully requested. The high-molecular aliphatic polyesters defined by claims 1, 5, 7, 10 and 29-31 and the processes for producing a high-molecular weight aliphatic polyester defined by claims 11, 18, 23, 24, 26 and 28 are neither anticipated by nor rendered obvious over Matsumoto et al.

Importantly, the present independent claims 1 and 11 recite specific properties of the high-molecular weight aliphatic polyester, for example, as having a ratio (Mw_2/Mw_1) of a weight average molecular weight (Mw_2) of the ring-opening (co)polymer after the chain lengthening to a weight average molecular weight (Mw_1) of the ring-opening (co)polymer before the chain lengthening of 1.65 to 10.00, a molecular weight distribution (Mw/Mn) of the ring-opening (co)polymer after the chain-lengthening reaction of 2.30 to 4.50, and a difference ($T_2 - T_1$) between a 1%-weight loss-starting temperature T_2 on heating of the ring-opening (co)polymer after the chain lengthening and a 1%-weight loss-starting temperature T_1 on heating of the ring-opening (co)polymer before the chain lengthening of 15°C to 30°C. A comparison of Examples 1 and 2 with Example 3 of the present specification shows that all of these properties are not inherent in any reaction of a ring-opening (co)polymer of glycolide and an oxazoline compound, or in any chain lengthening reaction, but are provided in a process as claimed, wherein, as in claim 11, the chain-lengthening reaction is conducted in the presence of the oxazoline compound

in a proportion within a range of 1 to 10 parts by weight per 100 parts by weight of the ring-opening (co)polymer, under the conditions specified in claim 11.

In making a rejection based on inherency, it is the burden of the Examiner to show that a prior art reference discloses all of the limitations necessary to inherently result in a product as claimed. MPEP §2112. The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic, *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q. 2d 1955, 1957 (Fed. Cir. 1993). The Federal Circuit in fact reversed a rejection in *Rijckaert* because the alleged inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art.

The Examiner has not met the requisite burden to make a rejection based on inherent teachings of Matsumoto et al. That is, in Example 6 relied upon by the Examiner in the Official Action, Matsumoto et al disclose that carboxyl end-capped PLLA (poly(L-lactic) acid) chips were obtained. This Example does not employ a ring-opening (co)polymer of glycolide or a mixture containing at least 70% by weight of glycolide and at most 30% by weight of another cyclic monomer. Thus, Example 6 of Matsumoto et al does not necessarily expressly or inherently describe all the limitations of the present claims.

Further, the Examiner also referred to paragraph [0010] of Matsumoto et al as disclosing the claimed molecular weight range. However, according to claims 1 and 11, the high-molecular weight polyglycolic acid product obtained by the chain-lengthening reaction has a weight average molecular weight of 181,000 to 500,000, and the ratio of this molecular weight, Mw_2 , to the molecular weight of the ring-opening polymer prior to chain lengthening, Mw_1 , is 1.65-

10.00. Other the other hand, in paragraph [0010], Matsumoto et al disclose that the “weight average molecular weight of the polylactic acid used in the present invention is preferably as high as possible, and is generally at least 50,000, preferably at least 80,000, preferably 100,000 to 300,000, more preferably 100,000 to 200,000.” Matsumoto et al are therefore describing their polylactic acid starting polymer which is then subjected to end capping. Matsumoto et al provide no teaching that the end-capping will result in a polymer having 1.65 to 10.00 times higher molecular weight. In fact, as Matsumoto et al refer to their starting polymer as having a molecular weight “as high as possible,” Matsumoto et al recognize that their end-capped product does not exhibit any appreciable or significant increase in molecular weight. Finally, the molecular weights in paragraph [0010] of Matsumoto et al are with reference to a polylactic acid starting polymer. Applicants find no teaching by Matsumoto et al of the molecular weight of a polyglycolide starting polymer or a polyglycolide end-capped polymer. Thus, Matsumoto et al do not necessarily disclose (1) a ring-opening (co)polymer of a polyglycolide before chain lengthening having a weight average molecular weight of at least 30,000, or (2) a high-molecular weight ring-opening (co)polymer product of a polyglycolide after chain lengthening (i) whose molecular weight has been increased by the chain-lengthening reaction to 181,000 to 500,000, (ii) having a ratio (Mw_2/Mw_1) of a weight average molecular weight (Mw_2) of the ring-opening (co)polymer after the chain lengthening to a weight average molecular weight (Mw_1) of the ring-opening (co)polymer before the chain lengthening of 1.65 to 10.00, and (iii) having a molecular weight distribution (Mw/Mn) ratio of a weight average molecular weight (Mw) of the ring-

opening (co)polymer, whose molecular weight has been highly increased by the chain-lengthening reaction, to a number average molecular weight (Mn) thereof of 2.30 to 4.50.

Importantly, as discussed in detail previously, as demonstrated by their viscosity data, and by their own admission, Matsumoto et al teach an end capping reaction, not a chain-lengthening reaction. Despite this clear teaching in Matsumoto et al, the Examiner asserts in the Official Action that no qualitative support is presented to show that Matsumoto et al result in a different product and it is unclear to the Examiner what limitations other than the claimed elements result in the claimed chain lengthening. However, as discussed in detail in previous responses, the only exemplary teaching of Matsumoto et al employing a glycolide polymer is Example 3. Accordingly, the Examiner's inherency rejection must be based on the inherent properties of the product of Matsumoto et al's Example 3 since, as noted, inherency cannot be based on optimization of disclosed conditions. Contrary to the presently disclosed process as recited in claim 11, Example 3 of Matsumoto et al does not employ oxazoline compound in a proportion within a range of 1 to 10 parts by weight per 100 parts by weight of the ring-opening (co)polymer. Moreover, Example 3 of Matsumoto et al does not disclose that the reaction time is 10 to 30 minutes. Further, Matsumoto et al disclose that unreacted end-capping reagent is contained in their product (see paragraph [0021]). Presumably, therefore, the product of Example 3 of Matsumoto et al contains such unreacted end-capping agent, thereby further indicating that Matsumoto et al's process and product differ from that of the presently claimed invention. Accordingly, the Examiner has not shown that Example 3 of Matsumoto et al necessarily results in the same product.

Just as identical processes may be presumed to provide identical products, products are generally presumed to be different from each other when their production processes are different. Accordingly, the reaction product of the ring-opening (co)polymer and the oxazoline compound as presently claimed is, from the evidence of record, presumed to be different from the product of Example 3 of Matsumoto et al in view of the difference in the amount of oxazoline incorporated therein, the end-capping agent contained in the product of Matsumoto et al, the unspecified reaction time of Matsumoto et al, and, importantly, the specific teachings of Matsumoto et al that a different product is obtained, supported by the melt viscosity data of Matsumoto et al.

At page 6 of the Official Action, the Examiner asserts “That Matsumoto discloses a different process is found moot since Applicant has not show said process to result in a different product.” However, Applicants only have a burden to show that the product is not inherent in the Matsumoto et al teachings if the Examiner shows that Matsumoto et al disclose the same process. As the Examiner admits the processes are different, there is no basis for the Examiner’s assertions of inherency.

While not wishing to be bound by theory, according to the end terminating method of Matsumoto et al, the aliphatic polyester resin and the end terminating agent are melted and kneaded at a high temperature, but are extruded by means of the twin-screw kneader extruder in a short kneading period of time. Therefore, the carboxyl end groups of the aliphatic polyester resin are terminated with the oxazoline compound, but a chain-lengthening reaction as presently claimed does not occur to a significant extent. On the other hand, according to the present

invention, the chain-lengthening reaction is caused by reacting the polyglycolic acid obtained by the ring-opening (co)polymerization of glycolide with the oxazoline compound at a high temperature of not lower than the melting temperature of the polyglycolic acid, but not higher than 300°C and in a reaction time of 10 to 30 minutes. As described in the present specification, the reaction with the oxazoline compound is a chain-lengthening reaction, in which a significant increase in the molecular weight of the ring-opening (co)polymer is observed, different from a mere chain-terminating reaction (page 15, lines 11-15).

In the present Official Action, the Examiner asserts that “the motivation to vary the time of reaction to increase the MW is as set forth previously.” In the Official Action of June 4, 2007, the Examiner merely concluded that since Matsumoto et al carry the reaction to completion, the same reaction is happening. Not only is the Examiner’s conclusion unsupported by the evidence of record, as Matsumoto et al teach that unreacted end-capping agent is contained in their product, it is opposite to the explicit teachings of Matsumoto et al. That is, Matsumoto et al disclose that an end-capping reaction occurs. Matsumoto et al do not disclose a chain-lengthening reaction occurs, or that a reaction can be conducted for a sufficient time and at a sufficient temperature to achieve a chain-lengthening reaction and molecular weight increase as claimed. Further, the melt viscosity data of Matsumoto et al does not indicate that a chain-lengthening reaction as presently claimed occurs, and Matsumoto et al do not recognize or indicate that any lengthening of reaction time will result in any different reaction, particularly a chain-lengthening reaction, or that a product having advantageous properties will result. Only in view of the Applicants’ specification can such conclusions be made.

Accordingly, Matsumoto et al do not disclose all of the limitations necessary to inherently result in a product as claimed. Therefore, Matsumoto et al do not anticipate the products defined by claims 1, 5, 7, 10 and 29-31. Moreover, Matsumoto et al do not render the processes defined by claims 11, 18, 23, 24, 26 and 28 obvious. That is, in determining patentability under 35 U.S.C. §103, it is necessary to determine whether there was an apparent reason to combine known elements in the fashion of the claims at issue, *KSR International Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740-41 (2007). Applicants find no evidence of record which would indicate any apparent reason to one of ordinary skill in the art to modify the teachings of Matsumoto et al to provide a chain-lengthening reaction product by reacting the polyglycolic acid obtained by a ring-opening (co)polymerization of glycolide with an oxazoline compound under conditions providing a chain-lengthened product. In fact, Matsumoto et al provide no recognition that any such chain-lengthening reaction could be conducted or that a chain-lengthened product having a desirable combination of properties could be obtained thereby.

In view of the deficiencies in the general teachings of Matsumoto et al and the deficiencies in the exemplary teachings of Matsumoto et al, it is clear that Matsumoto et al neither anticipate claims 1, 5, 7, 10 and 29-31 under 35 U.S.C. §102 nor render obvious claims 11, 18, 23, 24, 26 and 28 under 35 U.S.C. §103. Accordingly, the rejections based on Matsumoto et al have been overcome and reconsideration is respectfully requested.

Claims 1, 5, 7, 10, and 29-31 were rejected under 35 U.S.C. §103 as being unpatentable over the Shinoda et al U.S. Patent No. 5,247,013. The Examiner asserted that it would have been obvious to decrease the amount of methyl-glycoside additive taught by Shinoda in order to

increase the molecular weight and decrease the hydrolysis rate and that the claimed properties would be inherent in the composition of Shinoda.

This rejection is traversed and reconsideration is respectfully requested. Claim 1 recites a chain-lengthening reaction product of (a) a ring-opening (co)polymer of glycolide or a mixture containing at least 70% by weight of glycolide and at most 30% by weight of another cyclic monomer, and (b) an oxazoline compound having at least two oxazoline ring structures in its molecule, wherein the chain-lengthening reaction product is a chain-lengthened ring-opening polymer in which the oxazoline compound is bonded as a chain-lengthening agent. On the other hand, Shinoda et al provided no teaching or suggestion of any reaction product of oxazoline or obtained by reaction of oxazoline. In rejecting claim 1 based on Shinoda et al, the Examiner has improperly ignored significant limitations of claim 1.

Moreover, Applicants note that obviousness, required for a rejection under 35 U.S.C. §103, and inherency, on which the Examiner's reasoning rests, are entirely different concepts; the view that success would have been inherent cannot substitute for a showing of a reasonable expectation of success, *In re Rinehart*, 189 U.S.P.Q. 143, 148 (C.C.P.A. 1976). In the Examiner's inherency reasoning, Examples 1-3 of Shinoda et al are noted. However, these examples relate to lactide polymers, not glycolide polymers as presently claimed. Further, while Examples 10 and 11 of Shinoda et al employ glycolides, neither of these examples employ oxazoline as a reactant. Thus, whatever conclusion can be made as to the use of methyl glucoside by Shinoda et al is not relevant to claim 1, which is directed to a reaction product of oxazoline. Accordingly, there is no basis for assuming that the products of the Shinoda et al

examples exhibit the combination of properties recited in claim 1, that any modification of the Shinoda et al products would inherently exhibit the claimed combination of properties, or that any such modification or results thereof would reasonably be expected to be successful by one of ordinary skill in the art. Accordingly, Shinoda et al do not render the chain-lengthening reaction product of claims 1, 5, 7, 10 and 29-31 obvious under 35 U.S.C. §103, whereby the rejection is overcome. Reconsideration is respectfully requested.

Finally, claims 1, 5, 7, 10, 11, 18, 23, 24, 26, and 28 were rejected under 35 U.S.C. §103 as unpatentable over the Bonsignore U.S. Patent No. 5,470,944 in view of Matsumoto et al. The Examiner asserted that Bonsignore teach glycolic acid and lactic acid are functional equivalents and the motivation to use 0.5-2 wt% was set forth in the Official Action of June 4, 2007.

This rejection is traversed and reconsideration is respectfully requested. As noted, claim 1 recites a chain-lengthening reaction product of (a) a ring-opening (co)polymer of glycolide or a mixture containing at least 70% by weight of glycolide and at most 30% by weight of another cyclic monomer, and (b) an oxazoline compound having at least two oxazoline ring structures in its molecule, wherein the chain-lengthening reaction product is a chain-lengthened ring-opening polymer in which the oxazoline compound is bonded as a chain-lengthening agent.

On the other hand, Bonsignore is directed to the production of high molecular weight polylactic acid (at least about 25,000 and preferably above 50,000-100,000, column 6, lines 26-28) from lower molecular weight (2000-15,000, column 1, lines 11-18) versions. Bonsignore merely mentions polyglycolic acid is conventionally prepared by condensation polymerization or ring-opening polymerization and is environmentally compatible because it degrades to glycolic

acid. No other mention of polyglycolic acid is made and particularly no teaching or suggestion for production of high molecular weight polyglycolic acid is disclosed by Bonsignore. In fact, Bonsignore does not even state that glycolic acid and lactic acid are functional equivalents as asserted by the Examiner. Moreover, Bonsignore provides no basis or apparent reasoning for one of ordinary skill in the art to apply any of Bonsignore's teachings with respect to lactic acid to glycolic acid, particularly to obtain a product as presently claimed. To the contrary, the molecular weight of Applicants' starting material, the ring-opening (co)polymer before the chain lengthening, has a weight average molecular weight of at least 30,000, within the desired end product of Bonsignore.

On the other hand, as discussed in detail above, Matsumoto et al teach an end-capping reaction and are not directed to increasing molecular weight, but, rather, are directed to hydrolysis and heat resistance. Not only would one of ordinary skill in the art have no reason to combine the end-capping teachings of Matsumoto et al with the method of Bonsignore, such a combination does not result in either the presently claimed product, a chain lengthened ring-opening (co)polymer of glycolide of defined molecular weight, or the process of obtaining such. Finally, even if one of ordinary skill in the art were to employ glycolic acid in the lactic acid process of Bonsignore, although there is no apparent reasoning of record for doing so, there would be no expectation of a product having molecular weight properties as presently claimed. As noted above, inherency cannot substitute for a reasonable expectation of success. It is therefore submitted that the high-molecular weight aliphatic polyester and production process thereof defined by the present claims are nonobvious over the combination of Bonsignore and

Matsumoto et al. Accordingly, the rejection has been overcome, and reconsideration is respectfully requested.

It is believed that the above demonstrates the patentability of present claims 1, 5, 7, 10, 11, 18, 23, 24, 26 and 28-31, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Please charge any fees required in connection with the present communication, or credit any overpayment, to Deposit Account No. 503915.

Respectfully submitted,

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